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1635

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Title Immune Stimulatory Compositions and Methods for Use of Same to Enhance the Immune Response of a Host to an Antigen

ENCLOSURES (check all that apply)

☒ Fee Transmittal Form☐ Amendment/Response☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☐ Information Disclosure Statement, 1449 and
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Signature

Date

July 28, 2000

132. The method of claim 124, wherein the ISS-PN comprises a palindromic region comprising the sequence 5'-cytosine-guanine-3'.

133. The method of claim 132, wherein the palindromic region is at least 6 nucleotides in length.

134. The method of claim 133, wherein the palindromic region comprises the sequence 5'-purine-purine-C-G-pyrimidine-pyrimidine-3'.

135. The method of claim 133, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine-C-G-pyrimidine-pyrimidine-3'.

136. The method of claim 133, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine-C-G-purine-purine-3'.

137. The method of claim 124, wherein the ISS-PN comprises a sequence selected from the group consisting of AACGCC, AACGCT, AACGTC, AACGTT, AGCGCC, AGCGCT, AGCGTC, AGCGTT, GACGCC, GACGCT, GACGTC, GACGTT, GGCGCC, GGCGCT, GGCGTC, and GGCGTT.

138. The method of claim 124, wherein the ISS-PN comprises the sequence 5'-purine-T-C-G-pyrimidine-pyrimidine-3'.

139. The method of claim 124, wherein the ISS-PN comprises the sequence 5'-[TCG]_n-3', wherein n is any integer from 1 to 3.

140. The method of claim 124, wherein the ISS-PN administered to the skin or mucosa.

141. The method of claim 124, wherein the ISS-PN administered to muscle.

142. The method of claim 124, wherein the mammal is a human.

143. The method of claim 124, wherein the ISS-PN is a plasmid.
144. The method of claim 124, wherein the ISS-PN is a cosmid.
145. The method of claim 124, wherein the IgE production is associated with an allergy.
146. The method of claim 124, wherein the IgE production is associated with asthma.
147. A method for treating an antigen-stimulated IgE-related disorder in a mammal, comprising:
administering an immunostimulatory polynucleotide (ISS-PN) comprising the sequence 5'-cytosine-guanine-3' to a mammal sensitized to an antigen, said administering being in an amount sufficient to reduce IgE production stimulated by the antigen and treat the disorder in the mammal.
148. The method of claim 147, further comprising co-administering the antigen to the mammal.
149. The method of claim 148, wherein the antigen is encoded by a polynucleotide which is expressed in the mammal.
150. The method of claim 149, wherein the antigen-encoding polynucleotide comprises the ISS-PN.
151. The method of claim 148, wherein the antigen is a polypeptide.
152. The method of claim 147, further comprising co-administering to the mammal a polypeptide comprising an immunogenic epitope of the antigen.
153. The method of claim 147, further comprising co-administering to the mammal a polynucleotide for production of a polypeptide comprising an immunogenic epitope of the antigen.

154. The method of claim 153, wherein the polynucleotide comprises the ISS-PN.
155. The method of claim 147, wherein the ISS-PN comprises a palindromic region comprising the sequence 5'-cytosine-guanine-3'.
156. The method of claim 155, wherein the palindromic region is at least 6 nucleotides in length.
157. The method of claim 156, wherein the palindromic region comprises the sequence 5'-purine-purine-C-G-pyrimidine-pyrimidine-3'.
158. The method of claim 156, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine- C-G-pyrimidine-pyrimidine-3'.
159. The method of claim 156, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine- C-G-purine-purine-3'.
160. The method of claim 147, wherein the ISS-PN comprises a sequence selected from the group consisting of AACGCC, AACGCT, AACGTC, AACGTT, AGCGCC, AGCGCT, AGCGTC, AGCGTT, GACGCC, GACGCT, GACGTC, GACGTT, GGCGCC, GGCGCT, GGCGTC, and GGCGTT.
161. The method of claim 147, wherein the ISS-PN comprises the sequence 5'-purine-T-C-G-pyrimidine-pyrimidine-3'.
162. The method of claim 147, wherein the ISS-PN comprises the sequence 5'-[TCG]_n-3', wherein n is any integer from 1 to 3.
163. The method of claim 147, wherein the ISS-PN administered to the skin or mucosa.
164. The method of claim 147, wherein the ISS-PN administered to muscle.

165. The method of claim 147, wherein the mammal is a human.
166. The method of claim 147, wherein the ISS-PN is a plasmid.
167. The method of claim 147, wherein the ISS-PN is a cosmid.
168. The method of claim 147, wherein the IgE-related disorder is allergy.
169. The method of claim 147, wherein the IgE-related disorder is asthma.
170. A method for stimulating production of Th1 lymphocytes in a mammal, comprising:
administering an immunostimulatory polynucleotide (ISS-PN) to a mammal sensitized to an antigen,
wherein the ISS-PN comprises the sequence 5'-cytosine-guanine-3', said administering being in an amount
sufficient to stimulate production of Th1 lymphocytes.
171. The method of claim 170, further comprising co-administering the antigen to the mammal.
172. The method of claim 171, wherein the antigen is encoded by a polynucleotide which is
expressed in the mammal.
173. The method of claim 172, wherein the antigen-encoding polynucleotide comprises the ISS-
PN.
174. The method of claim 171, wherein the antigen is a polypeptide.
175. The method of claim 170, further comprising co-administering to the mammal a polypeptide
comprising an immunogenic epitope of the antigen.

176. The method of claim 170, further comprising co-administering to the mammal a polynucleotide for production of a polypeptide comprising an immunogenic epitope of the antigen.

177. The method of claim 176, wherein the polynucleotide comprises the ISS-PN.

178. The method of claim 170, wherein the ISS-PN comprises a palindromic region comprising the sequence 5'-cytosine-guanine-3'.

179. The method of claim 178, wherein the palindromic region is at least 6 nucleotides in length.

180. The method of claim 179, wherein the palindromic region comprises the sequence 5'-purine-purine-C-G-pyrimidine-pyrimidine-3'.

181. The method of claim 178, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine- C-G-pyrimidine-pyrimidine-3'.

182. The method of claim 178, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine- C-G-purine-purine-3'.

183. The method of claim 170, wherein the ISS-PN comprises a sequence selected from the group consisting of AACGCC, AACGCT, AACGTC, AACGTT, AGCGCC, AGCGCT, AGCGTC, AGCGTT, GACGCC, GACGCT, GACGTC, GACGTT, GGCGCC, GGCGCT, GGCGTC, and GGCGTT.

184. The method of claim 170, wherein the ISS-PN comprises the sequence 5'-purine-T-C-G-pyrimidine-pyrimidine-3'.

185. The method of claim 170, wherein the ISS-PN comprises the sequence 5'-[TCG]*n*-3', wherein *n* is any integer from 1 to 3.

186. The method of claim 170, wherein the ISS-PN administered to the skin or mucosa.
187. The method of claim 170, wherein the ISS-PN administered to muscle.
188. The method of claim 170, wherein the mammal is a human.
189. The method of claim 170, wherein the ISS-PN is a plasmid.
190. The method of claim 170, wherein the ISS-PN is a cosmid.
191. The method of claim 170, wherein the mammal is suffering from an allergy to the antigen.
192. The method of claim 170, wherein the mammal is suffering from antigen-related asthma.
193. A method for suppressing production of Th2 lymphocytes in a mammal, comprising:
administering an immunostimulatory polynucleotide (ISS-PN) to a mammal sensitized to an antigen,
wherein the ISS-PN comprises the sequence 5'-cytosine, guanine-3', said administering being in an amount
sufficient to suppress production of Th2 lymphocytes.
194. The method of claim 103, further comprising co-administering the antigen to the mammal.
195. The method of claim 194, wherein the antigen is encoded by a polynucleotide which is
expressed in the mammal.
196. The method of claim 195, wherein the antigen-encoding polynucleotide comprises the ISS-
PN.
197. The method of claim 194, wherein the antigen is a polypeptide.

198. The method of claim 193, further comprising co-administering to the mammal a polypeptide comprising an immunogenic epitope of the antigen.

199. The method of claim 193, further comprising co-administering to the mammal a polynucleotide for production of a polypeptide comprising an immunogenic epitope of the antigen.

200. The method of claim 199, wherein the polynucleotide comprises the ISS-PN.

201. The method of a claim 193, wherein the ISS-PN comprises a palindromic region comprising the sequence 5'-cytosine-guanine-3'.

202. The method of claim 201, wherein the palindromic region is at least 6 nucleotides in length.

203. The method of claim 201, wherein the palindromic region comprises the sequence 5'-purine-purine-C-G-pyrimidine-pyrimidine-3'.

204. The method of claim 201, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine- C-G-pyrimidine-pyrimidine-3'.

205. The method of claim 201, wherein the palindromic region comprises the sequence 5'-pyrimidine-pyrimidine-C-G-purine-purine-3'.

206. The method of claim 193, wherein the ISS-PN comprises a sequence selected from the group consisting of AACGCC, AACGCT, AACGTC, AACGTT, AGCGCC, AGCGCT, AGCGTC, AGCGTT, GACGCC, GACGCT, GACGTC, GACGTT, GGCGCC, GGCGCT, GGCGTC, and GGCGTT.

207. The method of claim 193, wherein the ISS-PN comprises the sequence 5'-purine-T-C-G-pyrimidine-pyrimidine-3'.

208. The method of claim 193, wherein the ISS-PN comprises the sequence 5'-[TCG]_n-3', wherein n is any integer from 1 to 3.
209. The method of claim 193, wherein the ISS-PN administered to the skin or mucosa.
210. The method of claim 193, wherein the ISS-PN administered to muscle.
211. The method of claim 193, wherein the mammal is a human.
212. The method of claim 193, wherein the ISS-PN is a plasmid.
213. The method of claim 193, wherein the ISS-PN is a cosmid.
214. The method of claim 193, wherein the mammal is suffering from an allergy to the antigen.
215. The method of claim 193, wherein the mammal is suffering from antigen-related asthma.